

REMARKS

This response, filed in reply to the Office Action dated December 22, 2008, is believed to be fully responsive to each point of the rejections raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 1-3 are all the claims pending in this application. Claims 1-3 are rejected.

Information Disclosure Statements

Applicants thank the Examiner for returning a signed copy of the PTO Form SB/08 that accompanied the Information Disclosure Statement filed March 22, 2006, indicating consideration of the references therein. Applicants note, however that the Examiner did not initial the non-patent literature documents. Applicants respectfully request that the Examiner acknowledged the non-patent literature documents and return a signed and initialed copy of the PTO Form SB/08 filed March 22, 2006.

Claims 1-3 are Rejected on the Ground of Nonstatutory Obviousness-type Double Patenting

On page 2, of the Office Action, Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1 and 5 of U.S. Patent No. 6,190,637 to Ino *et al.* in view of Toorongian *et al.* (Routine Production of 2-Deoxy-2-[18F]fluoro-D-glucose by Direct Nucleophilic Exchange on a Quaternary 4-Aminopyridinium Resin; Nucl. Med. Biol.; Vol. 17, No. 3, pages 273-279; 1990).

The Office Action states that the '637 Patent teaches a method for manufacturing a [F-18]-fluoride ion by bringing [O-18]-enriched water containing [F-18]-fluoride ion into contact with a weakly basic anion exchange resin. However, the Examiner acknowledges that the '637 Patent fails to teach the use of a quaternary amine resin, but asserts that Toorongian *et al.*

teaches a quaternary amine resin which allows the combination of the collection step, drying, and nucleophilic substitution reactions into a single and simpler procedure. The Office Action concludes that “it would have been obvious to one of ordinary skill in the art at the time of the invention to use a quaternary amine for the anion exchange taught by ‘637 because it simplifies the procedure and reduces the number of steps which would increase yield and decrease the amount of waste produced.”

Applicants respectfully disagree, and traverse the rejection on the following grounds.

The claimed invention is directed to the method for producing a radioactive fluorine compound wherein the ion exchange resin is represented by the formula recited in Claim 1. The method for producing a radioactive fluorine compound with the resin having the formula recited in Claim 1 synthesizes fluorine compounds in high yields. See Table 1; p. 23 of the specification.

The ‘637 Patent Claims teach a method for preparing [F-18]-fluoride ion wherein the [O-18]-enriched water is contacted with a strongly acidic cation exchange resin to remove impurity cation, and a weakly basic anion exchange resin. The ‘637 Patent fails to teach the ion exchange resin that is claimed in formula (1) of the instant claimed invention. The teachings of Toorongian *et al.* fail to cure the deficiency of the ‘637 Patent. First, Toorongian *et al.* fail to teach the resin having the formula recited in formula 1. Rather, Toorongian *et al.* teach a method which uses a column packed with quaternary -aminopyridinium resin, a structurally different resin from that claimed in the instant claimed invention. The use of quaternary -aminopyridinium resin has a number of drawbacks. For example, as stated on page 7 of the instant application, quaternary -aminopyridinium resin are highly hydrophilic and therefore expands with highly polar solvents and contract with solvents that are not very polar. Thus, if

the packed resin expands, the pressure in the column when the solvent is being passed therethrough becomes very high, resulting in the fluidity of the substrate containing solvent decreasing. Furthermore, the contraction causes deterioration of the column. Thus, one of ordinary skill in the art would not have been motivated to substitute the resin taught in the '637 Patent with the quaternary amine disclosed in Toorongian *et al.*

Further, the claimed invention is not obvious at least in view of the unexpectedly high production yields of fluorine compound, when compared to the yields of fluorine compounds produced by the method of Tooongian *et al.* Specifically, Table 1 of the instant specification teaches that fluoride ion resin collection rate for 1 gram of [18F]-containing [18O] water was 100 percent and for 5 gram of [18F]-containing [18O] water, the collection rate was 98.3, which are greater than the trapping efficiency results provided in Table 1 of the Toorongian *et al* publication. Thus, one of ordinary skill in the art would not have expected, nor reasonably predicted, that the resin as described in formula 1 of the claimed invention would produce unexpectedly high yields of fluorine compound, considering the yields disclosed in the art for other methods using different resins were significantly lower.

For the foregoing reasons, the '637 Patent Claims do not teach the method of producing radioactive fluorine compound using the ion exchange resin represented by formula 1 of the claimed invention. Moreover, the '637 Patent and Toorongian *et al.* taken alone or in combination, do not teach or suggest each and every limitation of Claims 1-3. Accordingly, a person skilled in the art could not have achieved the claimed invention even by combining the invention of the '637 Patent with the quaternary amine resin taught by Toorongian *et al.* Further,

in view of Applicants' unexpected high yield results, Applicants respectfully submit that the claims are not rendered obvious by the cited references.

Withdrawal of the rejection is respectfully requested.

Claims 1-3 are Rejected as being unpatentable under 35 U.S.C. § 103

On page 5 of the Office Action, Claims 1-3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the '637 Patent in view of the Toorongian *et al.* publication. The Office Action asserted essentially the same reasoning for rejecting Claims 1-3 under the provision of 35 U.S.C. § 103 as asserted under the ground of nonstatutory obviousness-type double patenting.

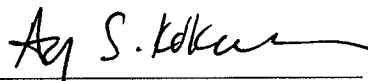
Applicants respectfully disagree, and traverse the rejection on the same ground as stated above. In summary, neither the '637 Patent nor the Toorongian *et al.* publication teach the method of producing radioactive fluorine compound using the ion exchange resin represented by formula 1 of the claimed invention. In view of Applicants' unexpected results, and the fact that one of ordinary skill in the art would not reasonably combine the cited references, Applicants respectfully submit that the claims are not rendered obvious by the cited references.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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CUSTOMER NUMBER

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